

**Science Advisory Board (SAB)
Supplemental Guidance for Assessing Cancer Susceptibility (SGACS) Review Panel
Teleconference Meeting
August 5, 2003 – U.S. EPA, Washington, DC**

Panel Members: See Panel Roster (Attachment A)

Date and Time: Tuesday, August 5, 2003, 3:00 to 5:00 p.m. EDT

Location: U.S. Environmental Protection Agency
Ariel Rios Federal Building, Room 6428
1200 Pennsylvania Avenue NW
Washington, DC 20005

Purpose: The purpose of this public teleconference meeting was for the panel to finalize its report on the EPA Office of Research and Development (ORD) draft document titled, "Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens" (SGACS).

Attendees:

Chair:	Dr. Henry Anderson
SAB Members:	Dr. James Klaunig Dr. Ulrike Luderer Dr. Richard Vetter
CHPAC Members:	Dr. Daniel Goldstein
SAP Members:	Dr. Christopher Portier
EPA SAB Staff:	Dr. Suhair Shallal Dr. Vanessa Vu

Other Persons Attending:

Helen Goeden, Minnesota Department of Health
Pam Shuback, Minnesota Department of Health
Hillary Carpenter, Minnesota Department of Health
Anne Krakowski, Minnesota Department of Health
Sandra Baird, Menzie-Cura and Associates
Nancy Beck, Office of Management and Budget (OMB)

Laura Solem, Minnesota Pollution Control Agency
Marco Bianchi, Michigan Department of Environmental Quality, Air Quality Division
Amy Miracle, Michigan Department of Environmental Quality, Air Quality Division
Pat Phibbs, BNA
George Oliver, Dow Agro Sciences
Steve Gibb, Risk Policy Report
R. Jeffrey Lewis, Exxon Mobil Biomedical Sciences
Lynn Ehrle, Cancer Prevention Coalition
Mary Beth Polley, CRC Press, Pesticide and Toxic News
Michael Formica, Chamber of Commerce
Kenneth Bogden, New York State Health Department
Dr. William Wood, Executive Director, U.S. EPA Risk Assessment Forum (RAF)
Dr. Hugh Barton, Experimental Toxicology Division, National Health and Environmental
Effects Research Laboratory, Office of Research and Development
(NHEERL/ORD), U.S. EPA

Meeting Summary

The meeting generally followed the schedule presented in the meeting agenda. (Attachment B)
The meeting adjourned at 4:30 p.m. EDT.

Roll Call and Opening

Dr. Suhair Shallal, Designated Federal Officer for SGACS, called the roll of panel members, asked other persons participating via telephone to identify themselves, welcomed participants to the teleconference, and provided brief background information about the panel formation process and about the availability of materials on the SAB website. Dr. Shallal pointed out that Drs. Handwerger, Heeringa, Marty and Sweeney were unable to participate in the call, and had indicated that they were happy with the status of the panel's report.

Welcome and Next Steps

Dr. Anderson welcomed participants to the call and expressed his gratitude to the panel members and the members of the public for their comments on drafts of the panel's report. He briefly reviewed the agenda for the teleconference, which included discussion of the draft report (Attachment C) and draft letter to the administrator (Attachment D).

Public Comments

One member of the public requested the opportunity to present comments. Mr. Lynn Ehrle of the Cancer Prevention Coalition, a nonprofit organization, commented on the SGACS review process. Mr. Ehrle noted that the SGACS draft report overlooked the important issue of early childhood cancer. He indicated that he had submitted references that should have been included.

Dr. Shallal assured Mr. Ehrle that all of his submissions had been forwarded to the panel members. Dr. Anderson thanked Mr. Ehrle for his comments and reminded everyone that the Agency's document deals with the issue of exposure during early-life stages to chemical carcinogens. He then proceeded to the discussion of individual questions.

Questions #1 and #2

Dr. Anderson invited comments from the panel on the response to Question #1; there were no comments.

Dr. Anderson invited comments from the panel on the response to Question #2. Dr. Shallal pointed out that Dr. Anderson had noted that the second sentence in the first paragraph ("The Panel disagrees . . .") might be changed to a recommendation for further research or analysis. Drs. Portier and Luderer said that they would not change that sentence. Dr. Shallal noted that it would stand as written. Dr. Portier pointed out that in the last paragraph on page 27 ("Because the data for nonmutagenic agents . . ."), the insertion of "that it is not possible to" was incorrect and should be deleted. Drs. Luderer and Anderson agreed and the change was made. Dr. Shallal re-read the change for confirmation. There were no additional comments on Question #2.

Questions #3 and #4

Dr. Anderson invited comments from the panel on the response to Question #3; there were no comments.

Dr. Anderson invited comments from the panel on the response to Question #4. Dr. Portier asked about the comments that had been inserted in the middle of page 30; Dr. Anderson indicated that the comments were all deleted. A brief discussion of the use of consistent language regarding endocrine-dependent or endocrine-responsive tumors followed.

Question #5

Dr. Anderson invited comments from the panel on the response to Question #5, noting that the language on statistical analysis had been improved; there were no comments.

Questions #6, #7 and #8

Dr. Anderson invited comments from the panel on the response to Question #6. Dr. Portier suggested that in the last paragraph on page 41, "should" should be changed to "might." Dr. Anderson agreed.

Anderson invited comments from the panel on the response to Question #7; there were no comments.

Dr. Anderson invited comments from the panel on the response to Question #8. Dr. Luderer recommended that all the suggestions be bulleted; Dr. Portier concurred. Dr. Goldstein recommended the headers be deleted. Dr. Portier recommended moving the statement “Specific suggestions, not in priority order” earlier in the response. Dr. Anderson agreed and restated the panel’s recommendations.

Dr. Anderson invited comments from the panel on Appendix 1 of the report; there were no comments.

Executive Summary

Dr. Anderson invited comments from the panel on the Executive Summary. He pointed out that the summary of the SGACS was now single-spaced and indented, and was clearly set apart from the text of the report. He said that the key part of the Executive Summary is the SAB recommendations.

Dr. Shallal asked the panel to consider the section addressing Question #2, namely, whether it would confuse the general reader to give an example of a chemical with a known mode of action and then say that the chemical supports the application of a default factor when the mode of action is unknown. Panel members indicated that the sentence was clear to them. Dr. Shallal suggested they consider the bullet point in isolation. Dr. Klaunig recommended changing “nonmutagenic mode of action” to “nonmutagenic chemicals.” Dr. Portier concurred and also suggested additional rewording. Panel members agreed to the changes, and Dr. Anderson re-read the language to confirm it.

Dr. Luderer noted that since the SGACS document discusses estrogen, not other hormones, that “endocrine” not be used in the Executive Summary. Dr. Portier recommended a change to “estrogen receptor agonists/antagonists” and Dr. Anderson agreed.

Dr. Portier recommended that in the section on Question #3 the last word in the first sentence, “assumptions,” should be changed to “approaches.” Dr. Anderson agreed. Dr. Portier suggested that the use of “recommends” in the section on Question #5 be changed to “suggests.” Drs. Luderer, Vetter, and Anderson agreed.

Regarding Question #6, Dr. Goldstein asked if the discussion of mode of action approaches required clarification. Following discussion, the panel members agreed with wording suggested by Dr. Portier, namely “development of approaches for addressing early life exposures for agents whose mode of action is through endocrine disruption, beginning with estrogenic agents.”

The panel then discussed the section addressing Question #8. Dr. Portier noted that the first bullet might be changed to state “in setting priorities.” Dr. Goldstein recommended reordering the sentence. Following discussion, Dr. Portier suggested language as follows: “For agents known to increase carcinogenic risk, carcinogenic potency and extent of exposure should be used in deciding which chemicals to study first for early life stage susceptibility.” The panel members

agreed. The panel members also discussed the first sentence in the section, which Dr. Goldstein commented implied a regulatory decision. Panel members agreed that the sentence might imply something about future policy and should be deleted. Finally, in the last bullet, Dr. Klaunig recommended changing “mechanism” to “mode” of action for consistency, and panel members concurred.

Letter to the Administrator

Dr. Anderson invited comments from panel members; he noted that many of the points already discussed were repeated in the letter. Dr. Shallal stated that the changes discussed in the Executive Summary would be made in the letter. The panel discussed the clarity of the language in the letter and determined that it was sufficiently clear.

Move to Transmit Report to the Executive Committee for Approval

Dr. Anderson remarked that the panel now had a final document and that unless there were objections, it would be finalized and sent to the Executive Committee for review at its October 1, 2003 meeting. Dr. Shallal polled the panel members for approval to send the report on for review, after the changes discussed in the teleconference were made. Drs. Vetter, Luderer, Portier, Goldstein, Klaunig, and Anderson all answered in the affirmative; Dr. Shallal noted that Drs. Heeringa, Handwerger, Marty and Sweeney had already given their approval.

Drs. Anderson and Shallal thanked the members of the panel for their work in preparing the report. The meeting was adjourned at 4:30 p.m. EDT.

Respectfully Submitted:

Certified as True:

/Signed/

/Signed/

Dr. Suhair Shallal
Designated Federal Officer
SGACS Review Panel
Science Advisory Board

Dr. Henry Anderson, Chair
SGACS Review Panel
Science Advisory Board

ATTACHMENTS

Attachment A	Roster of SGACS Review Panel Members http://www.epa.gov/sab/pdf/sgacsrproster.pdf
Attachment B	Meeting Agenda http://www.epa.gov/sab/03agendas/sgacsrp080503a.pdf
Attachment C	Draft Report, August 5, 2003 http://www.epa.gov/sab/pdf/sgacsnoedlinedraft080503.pdf
Attachment D	Draft Letter to the Administrator, August 5, 2003 http://www.epa.gov/sab/pdf/sgacsrevdraftnoedlter080503.pdf